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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,730	10/06/2006	Isidro Angelo Zarraga	59706US006	3329

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
10/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,730	ZARRAGA ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2,4,14,15 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,14,15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. The response filed 9/14/10 has been entered.

2. Applicant's arguments filed 9/14/10 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2, 4, 14, 15 and 18 are pending in this office action and claims 3, 5-13, 16-17 and 19-52 have been cancelled.

5. The objection to claims 1 and 18 because of the following informalities: The abbreviation IRM (Immune response modifier) and TLR (toll-like receptor) is withdrawn based on the amendment to the claims.

6. The rejection of claims 1-2, 4, 6 are 14-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to the claims.

7. The rejection of claims 1, 4, 6, 14-15 and 27 under 35 U.S.C. 102(b) as being anticipated by Hedenstrom et al. (US 2003/0045543) is withdrawn because Henderson fails to teach the new limitation "covalently attached" as required by the amendment to the claims.

8. The rejection of claims 1, 4, 6, 17, 28 and 32 under 35 U.S.C. 102(b) as being anticipated by Paal et al. (US 5,212,186) is withdrawn because Henderson fails to teach the new limitation "covalently attached" as required by the amendment to the claims.

9. Claims 1, 4, 6, 14-15, 17-18, 27 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg et al. (US 2003/0139364) is withdrawn because Henderson fails to teach the new limitation "covalently attached" as required by the amendment to the claims. For example claim 1 recite…that the polymer is a soluble polymer selected from poly(alkvlene glycols), poly(olefinic alcohols), polyvinylpyrrolidones. poly(hydroxyalkylmethacrylamides), poly(hydroxyalkylmethacrylates), polyvinyl alcohols. polyoxazolines, poly(acrylic acids), polyacrylamides, polyglutamates, polylysines. polysaccharides, and combinations thereof.

Claim Objections

10. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (i.e., claim 1).

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

New Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1, 2, 4, 14-15 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Wightman. (US 2004/0258698).

Wightman et al. teach with regards to instant claim 1, a method delivering an IRM complex (i.e., administering (thus delivering) the compound, see, [0074]) an immune response modifier (IRM) to treat patients suffering from cervical dysphasia and cervical

cancer/neoplasia (see 0078, as required by instant claims 14-15), wherein the IRM is covalently attached to a polymer (see 0008,) wherein the polymer is i.e., polyethylene glycol (i.e., a soluble polymer comprising alkylene oxide moiety; see 0191; as required by instant claims 1-2), and the IRM compounds are selected from imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, or 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo-quinolinamines and pyridinamines, imidazonaphthyridine or tetrahydroimidazonaphthyridine amines (as required by instant claim 1, see [0027].

Because Wightman specifically teach the same polymer attached to the IRM compound, it is reasonable that the complex has a molecular weight of 1 kDA-500 kDa (as required by instant claim 2) and therefore it would be expected that the IRM-polymer complex has a solubility of at least 0.1 microgram per milliliter in water under physiological conditions as required by instant claim 4, absent factual evidence to the contrary.

MPEP 2112.01 states that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), also “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.

Wightman et al. further teach that the IRM compound may be an agonist of a TLR comprising TLR7 and TLR8 (see 0025).

Therefore claims 1, 2, 4, 14-15 and 18 are anticipated by Wightman et al.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 14-15 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al. (US 2003/0139364) in view of Hoffman et al. (US 6,165,509) for the reasons made of record in Paper No. 20100514 and as follows. The rejection has been amended in view of Applicants amendment to the claims.

Applicant argues that Kreig does not teach covalent bonding of IRM compounds.

In response It should be noted that this is a rejection under 35 USC where the general conditions of a claim are disclosed in the prior art, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *See In re Keller,* 642 F 2d 413, 208 USPQ 871 (CCPA 1981)*; In re Merck &Co.,* 800 F.2d 1091, 231 USPQ (Fed. Cir. 1986).

Specifically Hoffman teaches that drugs are complexed with bioadhessive polymers through covalent bonding for administering/delivering to body fluids or mucosal tissues (see abstract). Hoffman further teaches that these polymers may be chosen from polyethylene glycol; polyacrylamide and polyvinyl pyrrolidone having molecular weight ranging from 10 kDa- 500 kDa (see col. 2, lines 20-28).

Thus argument is found not persuasive and the rejection is repeated below.

In Summary

Krieg et al teach administering via injecting to the injured tissue (i.e., delivering, see [0019] and [0369]) a treatment for cancers (i.e., as cervical cancer, lung cancer, melanoma etc [0199]), as required by instant claims 14-15) a pharmaceutical

composition comprising an IRM selected from the group of imidazoquinoline amines imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, or 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo-quinolinamines and pyridinamines, imidazonaphthyridine (as required by instant claims 1 and 14-15, see 0014) wherein the IRM compounds may be cross-linked with polyacrylic acids and polyvinyl pyrrolidone as required by instant claim 1, see [0371 and 0380]) wherein IRM may also be cross-linked with polymers that comprise alkylene oxide moieties (i.e., polyethylene glycol, see [0381] as required by instant claims 1). Because these polymers have functional groups that are able to form hydrogen bonds, it is reasonable that because the formulation is in water/aqueous solution it forma a covalent bond. Intrinsically it is reasonable to expect the solubility of the IRM-polymer to be at least 0.1 μg/ml in water under physiological conditions (as required by claim 4).

Krieg also teaches that the IRM is an agonist of TLR7 and TLR8 (as required by instant claim 18, see [0414]). Nonetheless Krieg is silent on the covalent bonding of the IRM to the polymer.

However Krieg et al. is silent about the IRM-polymer complex having a molecular weight of 1 kDa-500 kDa. Krieg also fails to teach that the IRM compound is an imidazoquinoline amide or consists of purines (as required by instant claim 28).

For that reason Hoffman et al is employed.

Hoffman teaches that drugs are complexed with bioadhessive polymers through covalent bonding for administering/delivering to body fluids or mucosal tissues (see abstract). Hoffman further teaches that these polymers may be chosen from

polyethylene glycol; polyacrylamide and polyvinyl pyrrolidone having molecular weight ranging from 10 kDa- 500 kDa (see col. 2, lines 20-28).

One of ordinary skill in the art would have been motivated to expand the method of administration/delivery of IRM compounds of Krieg et al. to a tissue to include other IRM compounds administered by Paal et al to be covalently bonded to the polymer. Because Hoffman teaches that drugs are complexed with bioadhessive polymers through covalent bonding, one of ordinary skill in the art would have been motivated to employ Krieg's IRM compounds and form a covalent bond with the polymers taught by both Krieg and Hoffman and deliver a bioadhessive drug to the mucosal area because Krieg teaches that these IRM-compounds are useful mucosal adjuvants (see 0338).

It would have been obvious to one of ordinary skill in the art to have employed the molecular weight of the IRM-polymer complex to be within the range of 1 kDa to 500-kDa because as taught by Hoffman these polymers have a molecular weight ranging from 10- 500 kDa. Since the IRM compounds are of low molecular weight (e.g., 314.17 for resoquimod, an IRM molecule) when conjugated to a polymer having a molecular weight of less than 500 kDa would necessarily result in a IRM-polymer complex having a molecular weight of less than 500 kDa.

Therefore one of ordinary skill in the art would have been motivated to expand the administration method of Krieg et al. and Paal et al. for IRM compounds crosslinked with polymer having molecular weight between 1-500 kDa because Hoffman teaches that these polymers have molecular weight ranging from 10-500 kDa.

Double Patenting

The terminal disclaimer filed by applicant is disapproved because of the wrong filing date. Therefore the rejection will be maintained.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, 14-15 and 18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **13 - 14** of U.S. Patent Application No. **12/304,339 as evident by** Krieg et al. (US 2003/0139364).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

- • The claims of the instant application '730 are drawn to a method of delivering one or more IRM compounds …. to a tissue comprising administering and IRM-polymer complex and the claims of the co-pending application '339 are drawn to a method of eliciting an antigen specific immune response in a subject comprising administering and IRM-PEG complex…. Both applications recite using the same compositions and/or derivatives thereof. Current application claims 1 and 32 recites the complex of an IRM may reasonable include PEG, therefore since the only required step is administering the complex one of ordinary skill in the art would reasonable expect that the claims of the instant application (which is broader) would reasonable encompass the claims of the copending application because the instant application teaches that the polymer may be a PEG polymer. Since both sets of claims are open ended(i.e., uses the term comprising) one of ordinary skill in the art would expect other active agents to be present in the method of delivery or method of eliciting and antigen response as evidence by Krieg et al.. Krieg et al. teach the composition of IRM-complex may include other active agents to give a synergistic effect of the immune response in a subject.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

14. Claims 1-2, 4, 14-15 and 18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1, 3, 12 and 14** of U.S. Patent Application No. **10/821,335.**

The claims of the instant application '730 are drawn to a method of delivering one or more IRM compounds .... to a tissue comprising administering and IRM-polymer complex and the claims of the co-pending application '335 are drawn to an IRM-support complex comprising an immune response modifier covalently bonded to a polymer which is an obvious variation of the instant claims, because merely delivering products are obvious variation for products.

One of ordinary skill in the art would have been motivated to use an IRM-support complex to deliver to a tissue with the expectation of reasonable amount of success because the same agents used in the copending application are employed in the instant application.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHI RLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
10/15/10

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628